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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,541

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Friedhelm Schonfeld

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1775

NOTIFICATION DATE

DELIVERY MODE

08/09/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No. 10/597,541	Applicant(s) SCHONFELD ET AL.	
	Examiner WILLIAM H. BEISNER	Art Unit 1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-51 and 59-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-51 and 59-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 30-51 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childers et al.(US 2004/0086872) in view of Glezer et al.(US 2004/0189311).

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With respect to claim 30, the reference of Childers et al. discloses an integrated lab-on-a-chip diagnostic system (Fig. 3) that includes an inlet (50) for a fluid sample; a lysis unit (118 or 120); a nucleic acid extraction unit (120 or 64); a reservoir (52) for containing a lysis fluid (114); a reservoir (52) for containing an eluent for removing nucleic acids collected in the extraction unit (110); wherein the sample inlet (50) is in fluid communication with the lysis unit (118 or 120); the lysis unit (118 or 120) is in fluid communication with the extraction unit (120 or 64); the reservoir (52) containing the lysis fluid (114) is in fluid communication with the lysis unit (118 or 120) and includes a valve (130) for fluid control; wherein the reservoir (52) for eluent (110) is in fluid communication with the extraction unit (120 or 64) and includes a valve (106) for fluid control. It is noted that the above components are formed on a common substrate (14, 160).

With respect to claim 30, while the reference of Childers et al. discloses the use of one or more pumps to push or pull fluid components through the fluid networks (paragraph [0099]), the reference does not specifically state that the system includes a single pump or syringe for actuation of all liquids.

The reference of Glezer et al. discloses that it is known in the art to selectively control the fluid movement within an assay cartridge (2390) similar to that of the reference of Childers et al. using a single pump (2345) (See Fig. 23 and paragraph [0256]).

In view of this teaching, it would have been well within the purview of one having ordinary skill in the art to employ the pump system suggested by the reference of Glezer et al. for controlling the fluid movement within the cartridge device of the primary reference of Childers et al. for the known and expected result of providing an art recognized means for controlling the

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fluid movement within an assay cartridge which is required of the system of the primary reference of Glezer et al.

With respect to claim 31, the reference of Childers et al. discloses a nucleic acid reaction unit (66) in fluid communication with extraction unit (120, 64).

With respect to claim 32, the reference of Childers et al. discloses a waste unit (56) in fluid communication with the lysis unit (118, 120).

With respect to claims 33-38, the reference of Childers et al. discloses a number of reservoirs (52) which are structurally capable of holding and/or functioning as required of claims 33-38. Note statements of intended use carry no patentable weight in apparatus type claims. Also note that the contents of the chambers cannot patentably distinguish the device over other prior art structures since the contents of the chambers is considered material worked on by the device (See MPEP 2115).

With respect to claims 39-42, the device of Childers et al. includes a filtration unit (120) are part of the lysis unit and/or connected to the lysis unit (See paragraphs [0063]-[0066]).

With respect to claims 43 and 44, the device of Childers et al. discloses the use of a heating device (paragraph [0065]). The use of conventional devices such as Peltier devices would have been well within the purview of one having ordinary skill in the art while providing the required heating and/or cooling suggested by the reference of Childers et al.

With respect to claims 43-47, the reference of Childers et al. discloses the use of particles and/or electrodes for nucleic acid retention or extraction (paragraphs [0066]-[0068]). The specifics of the particles and/or electrodes would have been clearly within the purview of one

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having ordinary skill in the art while providing the required nucleic acid retention and releasing actions.

With respect to claim 48, the device of Childers et al. is structurally capable of extracting nucleic acids from any of the sampled listed in the claim. Note statements of intended use carry not patentable weight in apparatus-type claims.

With respect to claims 49 and 50, the disclosed system of Childers et al. inherently meets the claim limitations of claims 49 and 50 since it is capable of being used and collecting biological and/or environmental samples (See paragraph [0104]).

With respect to claim 51, the device is considered to be disposable in the absence of further positively recited structure.

With respect to claims 59-61, the reference of Childers et al. reservoirs (52) in fluid communication with the inlet (50).

Response to Arguments

5. Applicant's arguments, see pages 5-9, filed 5/31/2011, with respect to the rejection of the claims over the reference of Pourahmadi et al.(US 6,440,725) have been fully considered and are persuasive. The rejection of the claims has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Childers et al.(US 2004/0086872) in view of Glezer et al.(US 2004/0189311).

Conclusion

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6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **WILLIAM H. BEISNER** whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael A. Marcheschi, can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1775**

WHB